

## PHARMACEUTICAL INSPECTION CONVENTION PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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## LIST OF PIC/S PARTICIPATING AUTHORITIES

(in the alphabetical order of the jurisdiction in which they are located)

NB: In PIC/S, the policy to refer to a Participating Authority is the following: geographical <sup>1</sup> name of the jurisdiction / name of the Agency (usually only the acronym).

	PARTICIPATING AUTHORITY	ACRONYM
Argentina	Instituto Nacional de Medicamentos (National Institute of Drugs)	INAME
Australia	Therapeutic Goods Administration	TGA
Austria	Austrian Agency for Health and Food Safety	AGES
Belgium	Agence Fédérale des Médicaments et des Produits de Santé (Federal Agency for Medicines and Health Products)	AFMPS
Bulgaria	Bulgarian Drug Agency	BDA
Brazil <sup>2</sup>	Agência Nacional de Vigilância Sanitária National Health Surveillance Agency	ANVISA
Canada	Health Canada - Regulatory Operations and Enforcement Branch (Santé Canada - Direction générale des opérations réglementaires et de l'application de la loi)	ROEB
Chinese Taipei	Taiwan Food and Drug Administration	TFDA
Croatia	Agency for Medicinal Products and Medical Devices of Croatia ( <i>Agencija za lijekove i medicinske proizvode</i> )	HALMED

The geographical name of the jurisdiction is neutral, as used on a classical world map with the exceptions of Chinese Taipei and Korea (Republic of).

The competence for GMP/GDP inspections in Brazil is shared between the central authority, National Health Surveillance Agency (ANVISA), and the Brazilian regional authorities, which count as one PIC/S Participating Authority. The Brazilian Local Health Surveillance considered as PIC/S Participating Authorities and represented in PIC/S by ANVISA are: Superintendência de Vigilância em Saúde – SUVISA/GO (State of Goiás); Diretoria de Vigilância em Medicamentos e Congêneres – DVMC (State of Minas Gerais); Secretaria de Estado da Saúde – SESA (State of Paraná); Superintendência de Vigilância Sanitária – SUVISA (State of Rio de Janeiro); Centro Estadual de Vigilância em Saúde – CEVS/ Divisão de Vigilância Sanitária – DVS (State of Rio Grande do Sul); Diretoria de Vigilância Sanitária – DIVS (State fo Santa Catarina) e; SIVISA Sistema de Informação em Vigilância Sanitária (State of São Paulo).

	PARTICIPATING AUTHORITY	ACRONYM
Cyprus	Pharmaceutical Services	CyPHS
Czech Republic <sup>3</sup>	Státní Ústav pro Kontrolu Léčiv (State Institute for Drug Control)	SÚKL
	Ústav pro Státní Kontrolu Veterinárních Biopreparátů a Léčiv (Czech Institute for State Control of Veterinary Biologicals and Medicines)	ISCVBM
Denmark	Danish Medicines Agency	DKMA
Estonia	State Agency of Medicines	SAM
Finland	Finnish Medicines Agency	FIMEA
France <sup>4</sup>	Agence nationale de sécurité du médicament et des produits de santé (French National Agency for Medicines and Health Products Safety)	ANSM
	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental & Occupational Health Safety)	ANSES
Germany <sup>5</sup>	Bundesministerium für Gesundheit (Federal Ministry of Health)	BMG
	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices)	ZLG
Greece	Εθνικός Οργανισμός Φαρμάκων (National Organization for Medicines)	EOF
Hong Kong SAR, China	Pharmacy and Poisons Board of Hong Kong	РРВНК
Hungary	National Institute of Pharmacy and Nutrition (NIPN)	NIPN
Iceland	The Icelandic Medicines Agency	IMA
Indonesia	Indonesian Food and Drug Authority	Badan POM
Iran	Iran Food and Drug Administration	IFDA
Ireland	Health Products Regulatory Authority	HPRA
Israel	Institute for the Standardization and Control of Pharmaceuticals	ISCP
Italy <sup>6</sup>	Agenzia Italiana del Farmaco	AIFA
	Directorate General for Animal Health and Veterinary Medicinal Products (Direzione generale della sanità animale e dei farmaci veterinari)	DGSAF

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<sup>&</sup>lt;sup>3</sup> SÚKL and ISCVBM count as two distinct Participating Authorities.

<sup>&</sup>lt;sup>4</sup> ANSM and ANSES count as two distinct Participating Authorities.

<sup>&</sup>lt;sup>5</sup> BMG and ZLG count as one Participating Authority. All German Medicinal Authorities, which are listed on the ZLG web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by ZLG.

<sup>&</sup>lt;sup>6</sup> AIFA and DGSAF count as two distinct Participating Authorities.

	PARTICIPATING AUTHORITY	ACRONYM
Japan <sup>7</sup>	Ministry of Health, Labour and Welfare	MHLW
	Pharmaceuticals and Medical Devices Agency	PMDA
	Japanese Prefectures	-
Korea (Republic of)	Ministry of Food and Drug Safety	MFDS
Latvia	Zāļu Valsts Aģentūra (State Agency of Medicines)	ZVA
Liechtenstein	Amt für Gesundheit (Office of Healthcare)	AG
Lithuania	State Medicines Control Agency	SMCA
Malaysia	National Pharmaceutical Regulatory Agency	NPRA
Malta	Malta Medicines Authority	MMA
Mexico	Federal Commission for the Protection Against Sanitary Risks (Comisión Federal para la Protección contra Riesgos Sanitarios)	COFEPRIS
Netherlands <sup>8</sup>	Inspectie Gezondheidszorg en Jeugd (Health and Youth Care Inspectorate)	IGJ
New Zealand	Medicines and Medical Devices Safety Authority	Medsafe
Norway	Norwegian Medicines Agency	NOMA
Poland	Chief Pharmaceutical Inspectorate	CPI
Portugal	Autoridade Nacional do Medicamento e Produtos de Saúde IP (National Authority of Medicines and Health Products IP)	INFARMED IP
Romania	National Agency for Medicines and Medical Devices of Romania	NAMMDR
Saudi Arabia	Saudi Food and Drug Authority	SFDA
Singapore	Health Sciences Authority	HSA
Slovak Republic	State Institute for Drug Control	SIDC
Slovenia	Agency for Medicinal Products and Medical Devices	JAZMP
South Africa	South African Health Products Regulatory Authority	SAHPRA
Spain <sup>9</sup>	Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices)	AEMPS

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MHLW, PMDA and the Japanese Prefectures count as one Participating Authority. The Japanese Prefectures are represented by MHLW.

The competence for GMP/GDP inspections in the Netherlands is allocated to the central authority, Dutch Health and Youth Care Inspectorate (IGJ). IGJ is the PIC/S Participating Authority representing GMP/GDP for human as well as veterinary medicinal products. IGJ performs national and international GMP/GDP inspections representing the Health and Youth Care Inspectorate - Pharmaceutical Affairs as well as the Medicines Evaluation Board - Veterinary Medicinal Products Unit, which is mandated to issue GMP certificates on behalf of the Ministry of Economic Affairs.

The competence for GMP/GDP inspections in Spain is shared between the central authority, Spanish Agency for Medicines and Medical Devices (AEMPS), and the Spanish regional authorities, which count as one PIC/S Participating Authority. All Spanish Medicinal Authorities, which are listed on AEMPS' web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by AEMPS.

	PARTICIPATING AUTHORITY	ACRONYM
Sweden	Swedish Medical Products Agency	MPA
Switzerland	Swiss Agency for Therapeutic Products	Swissmedic
Thailand	Food and Drug Administration	Thai FDA
Turkey	Turkish Medicines and Medical Devices Agency	TMMDA
Ukraine	State Service of Ukraine on Medicines and Drugs Control	SMDC
United Kingdom <sup>10</sup>	Medicines and Healthcare Products Regulatory Agency	MHRA
	Veterinary Medicines Directorate	VMD
United States of America	United States Food and Drug Administration	US FDA

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<sup>10</sup> MHRA and VMD count as two distinct Participating Authorities.